UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

OPTIGENEX INC.,

Civil Action No.: 14-CV-6558 (ALC)

Plaintiff,

ν.

BHIP GLOBAL, INC.,

Defendant.

PLAINTIFF OPTIGENEX INC.'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR PRELIMINARY INJUNCTION

Respectfully submitted,

DAVIDOFF HUTCHER & CITRON LLPAttorneys for Plaintiff Optigenex Inc.

By: Michael A. Adler, Esq. (MA6626) Jonathan E. Temchin, Esq. (JT 7609) 200 Garden City Plaza, Suite 315 Garden City, New York 11530 (516) 248-6400

TABLE OF CONTENTS

Contents

I.	P	reliminary Statement	1
II.	S	ummary of the Facts and Argument	2
III.		Statement of Relevant Facts	5
	A.	General Background of Optigenex and its Intellectual Property	5
]	B.	The License Agreement	7
(C.	bHIP's Continuing and Ongoing Misappropriation of the Optigenex Trademarks By Using them in Connection with Unauthorized Products	9
	(i) the product label, packaging, advertising and marketing materials were not reviewed and approved by Optigenex and thus violated the License Agreement	
	(ii) the product lacks the minimum efficacious daily amount of ac-11®	10
	(iii) the FUSION product line was not licensed	11
	7	The FIX Product	12
	(Other Products	13
IV	. (Controlling Principals of Law and Argument	14
	A.	Standard for Preliminary Injunction	14
]	В.	Irreparable Harm	14
(C.	Likelihood of Success on the Merits	16
	1	. Trademark Infringement	16
	2		
	D.	Balance of Hardships Tips Decidedly in Favor of Optigenex	
V.		Conclusion	

TABLE OF AUTHORITIES

Cases

Church of Scientology Int'l v. Elmira Mission of the Church of Scientology, 794 F. 2d 38 (2d Cir. 1986)	15
Citigroup Global Mkts., Inc. v. VCG Special Opportunities Master Fund, Ltd., 598 F.3d 30 (2d Cir. 2010)	
Fido's Fences Inc. v. Canine Fence Co., 309 Fed. App'x 480 (2d Cir. 2009)	15
Frank Brunckhorst Co. v. G. Heileman Brewing Co., Inc., 875 F. Supp. 966 (E.D.N.Y. 1994)	16
Krispy Kreme Doughnut Corp. v. Satellite Donuts, LLC, 725 F. Supp. 2d 389 (S.D.N.Y. 2010)	14
L & L Wings, Inc. v. Marco-Destin, Inc., 676 F. Supp. 2d 179 (S.D.N.Y. 2009)	16
Lois Sportswear, U.S.A., Inc. v. Levi Strauss & Co., 799 F.2d 867 (2d Cir. 1986)	16
Microban Prods. Co. v. API Indus., Inc., No. 14 Civ. 41, 2014 WL 1856471 (S.D.N.Y. May 8, 2014)	16
People's United Bank v. PeoplesBank, 401 Fed. App'x 607 (2d Cir. 2010)	14
Power Test Petroleum Distributors, Inc. v. Calcu Gas, Inc., 754 F.2d 91 (2d Cir. 1985)	14
Sunward Elecs., Inc. v. McDonald, 362 F.3d 17 (2d Cir. 2002)	16
Statutes	
15 U.S.C. 8 1125	16

Michael A. Adler (MA6626) Jonathan E. Temchin (JT7609)

DAVIDOFF HUTCHER & CITRON LLP

200 Garden City Plaza, Suite 315

Garden City, NY11530

Telephone: (516) 248-6400 Fax: (516) 248-6422 maa@dhclegal.com

jet@dhclegal.com

Attorneys for Plaintiff

UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

OPTIGENEX INC.,

Plaintiff,

v.

BHIP GLOBAL, INC.,

Defendant.

Civil Action No.: 14-CV-6558 (ALC)

PLAINTIFF OPTIGENEX INC.'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR PRELIMINARY INJUNCTION

PLAINTIFF OPTIGENEX INC.'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR PRELIMINARY INJUNCTION

I. Preliminary Statement

Plaintiff Optigenex Inc. ("Plaintiff" or "Optigenex") respectfully submits this Memorandum of Law in support of its motion for preliminary injunction against Defendant bHIP Global, Inc. ("Defendant" or "bHIP"), resulting from bHIP's unauthorized, notorious and ongoing conduct in marketing and offering for sale consumer products that are improperly being associated by bHIP with Optigenex's trademarks and Optigenex's patented, all-natural, thoroughly tested and safe cellular DNA repair ingredient derived from the rainforest plant *Uncaria*, typically the *Uncaria tomentosa* species thereof ("ac-11®" or the "ac-11® Ingredient")

Such unauthorized products are falsely associated with Optigenex, causing irreparable damage to Optigenex and its reputation as the preeminent global leader in all-natural, cellular DNA repair.

Optigenex brings the instant motion for preliminary injunction in accordance with 35 U.S.C. § 283, Rule 65 of the Federal Rules of Civil Procedure and Section 3.7.2 of the License Agreement. In connection therewith, Optigenex submits the Declaration of Dan Zwiren (the "Zwiren Dec."), President and Chief Executive Officer of Optigenex, the Declaration of Lee Anthony Worth (the "Worth Dec.")¹, Managing Director of Optigenex, and the Declaration of Michael A. Adler, Esq. and the exhibits annexed thereto.

II. Summary of the Facts and Argument

Until recently, bHIP was a trademark licensee of Optigenex under the terms of an April 22, 2011 Supply and Limited Trademark License Agreement (the "License Agreement") between Plaintiff and Defendant. (Exhibit D). On September 6, 2014, Optigenex terminated the License Agreement based on numerous material breaches by bHIP. During the term of the License Agreement, bHIP marketed and sold several products in association with Optigenex's U.S. registered trademarks and U.S. issued patents that were never authorized under the License Agreement.

Notwithstanding termination of the License Agreement on September 6, 2014, bHIP today notoriously continues to market, distribute, offer for sale and sell these same unauthorized products. (Zwiren Dec., ¶20). In so doing, bHIP misappropriates Optigenex's intellectual property, and thereby each day causes irreparable harm to Optigenex in the ways that are shown herein below, as well as by the accompanying declarations and exhibits in support of this motion.

¹ At times, this memorandum references specific sections of the Zwiren and Worth declarations. However, the instant memorandum incorporates all of these declarations.

Briefly summarized, the ongoing acts by bHIP that are causing irreparable harm to Optigenex include the following:

- 1. Without authority or approval from Optigenex, bHIP markets and sells a weight loss product called "FUSION" that bHIP advertises as "powered by" Optigenex's proprietary, trademark protected ac-11[®] ingredient. (Exhibit E; Zwiren Dec., ¶12; Worth Dec., ¶¶30, 32).
- 2. During the term of the License Agreement, FUSION was sold by bHIP in direct violation of bHIP's contractual obligation to submit all proposed labels and advertising beforehand for Optigenex pre-approval. (Exhibit D). Under the License Agreement, bHIP's failure to obtain such pre-approval, in and of itself, would have rendered the FUSION product unauthorized. Even assuming, *arguendo*, the product otherwise had approval from Optigenex which it did not bHIP today continues to sell FUSION *powered by ac-11*® without authorization from Optigenex and notwithstanding termination of the License Agreement. (*Id*).
- 3. bHIP's failure to obtain Optigenex pre-approval of bHIP's labels and advertising for FUSION was not a relatively harmless breach of "formalities."
- (a) The FUSION label reflects that the product contains *significantly less* than what was contractually stipulated by the parties as the required minimum amount of ac-11[®] on a daily serving basis to be contained in any ac-11[®] -based product sold by bHIP. (Exhibit E). This lapse, which was left unknown to Optigenex by virtue of bHIP's failure to submit the label to Optigenex for review, was critical, because, as the parties contractually agreed, the stipulated minimum amount of ac-11[®] per daily serving is dictated by published research establishing minimum levels necessary for therapeutic efficacy of the ingredient.

- (b) The License Agreement prohibited the sale of beverages containing ac-11[®]. (Exhibit D). Although ac-11[®] is recognized as a "dietary supplement," as that term is defined by the U.S. Food and Drug Administration ("FDA"), ac-11[®] is neither a "food" nor a FDA approved "food additive." Notwithstanding, bHIP's labels and advertising for FUSION, which were never submitted as required for review to Optigenex, it is unclear and confusing to the consumer if FUSION is a "dietary supplement" for consumption, with water or is a "meal replacement shake," as FUSION's label suggests, i.e., a food in powdered beverage form. (Exhibit E; Worth Dec. ¶¶30-32).
- (c) In direct violation of the License Agreement, the FUSION label and advertising failed to identify the ac-11® patents, nor did they attribute ownership of the ac-11® Mark to Optigenex. (Exhibits D and E).
- (d) bHIP markets FUSION as a single product "kit" containing a companion thermogenic weight loss product called "FIX." (Zwiren Dec., ¶36; Worth Dec., ¶53-59). (Zwiren Dec., ¶31). Neither the joint FUSION/FIX marketing materials nor the FIX label were ever submitted for review by Optigenex. Recent examination by Optigenex of the FIX labeling shows that there are significant nutrition labeling errors and erroneous "Supplement Facts" statements on the FIX label. (Worth Dec., ¶53-59). Among other things, these errors render the product, i.e., "FUSION + FIX," as bHIP calls it, "non GMP, i.e., not in accordance with industry recognized and accepted Good Manufacturing Practices. Such packaging violated the License Agreement, because GMP compliance by bHIP specifically was required thereunder. (Exhibit D, Worth Dec., ¶59).

- 4. For these reasons, had the FUSION and FIX labels and advertising been submitted, as required, to Optigenex, they would have been rejected. Under the License Agreement, failure to submit those materials rendered FUSION unauthorized.
- 5. The failure of bHIP to pre-submit for Optigenex approval advertising and marketing messages for several other ac-11[®]-based products, specifically, "AEDRE," "PURPLE CAPS," "PURPLE PLUS," "PURPLE STRIPS" and "ACTIVAR," also rendered those products unauthorized during the term of the License Agreement. (Exhibits D, L and M; Worth Dec., ¶60-69; Zwiren Dec., ¶53). For the same reasons as apply to FUSION, bHIP neither had, under the License Agreement, nor has today, now that the License Agreement is terminated, any right to use the Optigenex trademarks in connection with those products.

III. Statement of Relevant Facts

A. General Background of Optigenex and its Intellectual Property

Optigenex is an applied sciences and nutritional supplements company dedicated to healthy age management and is recognized, *inter alia*, as a leader in all-natural, cellular DNA repair, anti-tumor, anti-inflammatory and immuno-enhancement technology. (Exhibit C; Zwiren Dec., ¶4). Through substantial investment, research and development, advertising, marketing and sales, Optigenex, and its predecessors-in-interest, took significant steps and expended substantial resources to protect the quality of the ac-11[®] Ingredient as well as its famous trademarks associated with the ac-11[®] Ingredient. (Zwiren Dec., ¶¶6, 7; Worth Dec., ¶¶14-18).

The ac-11[®] Ingredient is an all-natural, thoroughly tested and safe extract derived from the rainforest plant *Uncaria*, typically the *Uncaria tomentosa* species thereof. Optigenex owns ten (10) U.S. patents, namely, U.S. Patent Nos. 6,039,949, 6,238,675, 6,361,805, 6,964,784,

7,579,023, 7,595,064, 7,947,312, 7,955,626, 8,372,448 and 8,372,449 (collectively, "Optigenex's Patents"), as well as numerous foreign patents and patent applications directed to *inter alia*, the ac-11[®] Ingredient and the methods of preparation thereof. (Exhibit A; Zwiren Dec., ¶6). Optigenex is also the sole owner of all right, title and interest in numerous trademarks and trademark registrations in the United States and elsewhere for the marks **OPTIGENEX**, **ACTIVAR** and **AC-11** ("Optigenex's Trademarks"), including U.S. Registration Nos. 3,484,992 for **OPTIGENEX** (double helix design), 2,930,140 for **AC-11** (word), 3,152,471 for **ACTIVAR** (word), 3,329,324 for **AC-11** (oval design), 3,388,037 for **AC-11** (rectangle design) and 3,227,914 **DNA HELIX** (design).(Exhibit B, Zwiren Dec., ¶7). In its answer, bHIP admits that Optigenex is the owner of all right, title and interest in the '140 and '324 registrations. (Docket No. 9, ¶14).

Optigenex licenses, markets, advertises, makes, uses, sells and/or offers for sale the ac-11® Ingredient as well as products incorporating the ac-11® Ingredient (the "ac-11® Products") in association with the world-famous Optigenex Trademarks. (Worth Dec., ¶¶14-18). The Optigenex Trademarks are used in association with Optigenex's website and Optigenex's products sold directly by Optigenex or through Optigenex's distributors. (*Id.*). Vendors, suppliers, licensees and consumers associate the Optigenex Trademarks with Optigenex, and the ac-11® Ingredient and ac-11® Products as originating from Optigenex. (*Id.*). Vendors, suppliers, licensees and consumers appreciate that Optigenex's Trademarks denote products originating from Optigenex and associate a high level of quality with the ac-11® Products. (*Id.*).

The substantial goodwill, customer recognition and business reputation that Optigenex developed since 1997 are predicated largely on the quality (and quality control) of the ac-11[®] Ingredient and Products being associated with the Optigenex Trademarks. (*Id.*). Because of

Optigenex's efforts, the Optigenex Trademarks enjoy a distinct association in the United States and worldwide with the ac-11[®] Ingredient and ac-11[®] Products, which products are known to be the premier DNA repair products. (*Id.*). Optigenex expended, and continues to expend, significant resources in maintaining control over the quality of the ac-11[®] Ingredient and Products associated with the Optigenex Trademarks to ensure that they meet precise quality control standards and enhance the goodwill associated with the Optigenex Trademarks. (*Id.*). As a result of the above, the Optigenex Trademarks are recognized in the United States and in numerous countries around the world as being associated with the products and the scientific literature (including the scientific and clinical research studies) originating from, and/or on behalf of, Optigenex. (*Id.*).

B. The License Agreement

bHIP was the exclusive licensee in the Multi-Level Marketing ("MLM") distribution channel of Optigenex for the ac-11[®] Ingredient and Products in the United States. (Exhibit D, Zwiren Dec., ¶10). Pursuant to Section 2.4.1 of the License Agreement, Defendant was granted a license to market, advertise and offer for sale *authorized* ac-11[®] Products in the MLM distribution channel in association with Optigenex's Trademarks. (Exhibit D, Section 2.4.1).In connection with bHIP's marketing and offering for sale ac-11[®] Products, the License Agreement imposes certain obligations on bHIP to ensure that the ac-11[®] Products adhere to the strict quality control standards that the public commonly associates with Optigenex and Optigenex's Trademarks. (Exhibit D). The nature of the ac-11[®] Products itself, whether as a dietary supplement or in some other form, and the ingredients contained therein and manner in which bHIP markets the ac-11[®] Products were, and continue to be, of special importance to Optigenex

prompting the strict standards enunciated in the License Agreement. (Exhibit D; see generally Zwiren and Worth Decs.).

For example, the License Agreement carved out certain types of products as "authorized" and others types of products as "unauthorized." (Exhibit D, see generally Sections 1.1(e), 2.4.3, 3.4, 3.5, 6.4 and Schedule B). The term "Authorized Products" was defined in the License Agreement as "products containing the ac-11® Ingredient listed in Schedule B that may be manufactured and sold in accordance with the License Agreement...Products containing ac-11® other than those listed in Schedule B are unauthorized under this Agreement." (*Id.* at Section 1.1(e)). Schedule B lists certain products that were expressly authorized under the License Agreement. (*Id.* at Schedule B). Schedule B did not permit bHIP to market or offer for sale beverage or meal products containing the ac-11® Ingredient. (Id.). Indeed, Section 2.4.3 of the License Agreement stated that beverage products containing ac-11® were not authorized under the License Agreement. (*Id.* at Section 2.4.3).

To ensure that bHIP marketed and offered for sale only products that were expressly authorized by the License Agreement, the parties structured the License Agreement to impose strict quality control standards. Section 3.5. *et seq.* expressly prohibited bHIP from manufacturing or offering for sale products containing the ac-11[®] Ingredient in an unauthorized form, such as sun care products and food products. (*Id.* at Section 3.5). Moreover, the parties agreed to grant Optigenex the authority to review and approve any product packaging, labeling, advertising and marketing support materials containing the ac-11[®] Ingredient. (*Id.* at Section 6.4). To that end, bHIP was obligated to submit any such material to Optigenex for preapproval. (*Id.*). If bHIP failed to do so, then the product was an unauthorized product.(*Id.*).

The License Agreement set forth specific remedies in the event that bHIP marketed or offered for sale an unauthorized product. Under Section 3.7.2 and 11.1.2, the parties agreed that the manufacture and/or offering for sale of unauthorized products by bHIP and/or the violation of Optigenex's Patents or Trademarks may irreparably harm Optigenex and damages are not quantifiable. (*Id.* at Sections 3.7.2 and 11.1.2). Optigenex also has the right to seek equitable relief in addition to any other remedy at law for damages.(*Id.*).

C. bHIP's Continuing and Ongoing Misappropriation of the Optigenex Trademarks By Using them in Connection with Unauthorized Products

Section 3.5.1 of the License Agreement states:

This Agreement authorizes and conveys certain rights in respect of the sale of Authorized Products in certain Distribution Channels and in certain Territories. bHIP shall not manufacture or sell, nor shall it permit to be manufactured or sold, any product containing the ac-11[®] Ingredient that does not qualify as an Authorized Product. The sale of any product, even a product otherwise considered to be an Authorized Product, outside of the Distribution Channels and/or Territories will render that product unauthorized.

(*Id.* at Section 3.5.1). An unauthorized product is one that is non-compliant with specific characteristics required under the terms of the License Agreement. For purposes of the instant motion these characteristics, *inter alia*, are:

- (i) the product label, packaging, advertising and marketing materials were not reviewed and approved by Optigenex (*Id.*at Section 6.4.1);
- (ii) the product lacks the minimum efficacious daily amount of ac- $11^{\text{@}}$ (*Id.* at Section 3.4.1); or
 - (iii) the product line is not licensed (see generally id.).

Each of these characteristics are separately discussed below, but all render bHIP's FUSION and other products unauthorized.

(i) the product label, packaging, advertising and marketing materials were not reviewed and approved by Optigenex and thus violated the License Agreement

bHIP markets a product called FUSION as one containing ac-11[®], but the FUSION product is unauthorized. Section 6.4.1 of the License Agreement stated:

Proposed product packages, labels, advertising and marketing support materials must be submitted by bHIP in advance of production to Optigenex for preapproval as to form and content in respect of the statement of ingredients, identification and description of ac-11[®], ac-11[®] claims made, notation of the ac-11[®] Mark in accordance with the requirements of Schedule B, statement of ownership of the Mark and listing of patents. Any product as to which the packages, labels advertising or support materials have not been submitted shall be deemed to be an Unauthorized Product. Similarly, any claim made as to the efficacy of ac-11[®] that has not been preapproved by Optigenex will render the product involved unauthorized.

(*Id.* at Section 6.4.1). (emphasis added). At no time during the pendency of the License Agreement did bHIP submit the unauthorized FUSION product for approval. (Zwiren Dec., ¶13; Worth Dec., ¶29-32). Similarly, no publicity, advertising or marketing materials were submitted. (Zwiren Dec., ¶13). Accordingly, the FUSION product is an unauthorized product under the License Agreement for this reason alone.

(ii) the product lacks the minimum efficacious daily amount of ac-11®

The FUSION product contains less than the minimum efficacious daily amount of ac-11[®] required for ac-11[®] products under the License Agreement. (Worth Dec., ¶¶42-43). The minimum efficacious daily dosage of ac-11[®] was stipulated by the parties in the License Agreement as the minimum amount, as shown by research studies, that must be taken to substantiate the therapeutic claims for ac-11[®] made by Optigenex and carried by bHIP on its product labels. (Exhibit D, Section 3.4.1; Worth Dec., ¶¶42-43). Pursuant to Section 6.4.1 of the License Agreement "[A]ny claim made as to the efficacy of ac-11[®] that has not been preapproved by Optigenex will render the product involved unauthorized." (Exhibit D, Section

6.4.1). The minimum efficacious amount of ac-11[®] for the FUSION product per serving is 250 mg, but it only contains 125 mg. (Exhibit E; Worth Dec., ¶¶42-43). FUSION has not been so pre-approved. (Worth Dec., ¶¶42-43). Accordingly, the FUSION product is an unauthorized product pursuant to the terms of the License Agreement.

Specifically, the "Supplement Facts" label for FUSION reflects that a single serving of FUSION purports to contain 125 mg of ac-11[®]. (Exhibit E). In its answer to Optigenex's complaint, bHIP admits that the supplement facts on the label for FUSION that 125 mg of the ac-11[®] Ingredient is included in each serving of FUSION. (Docket No. 9, ¶36). bHIP's label is silent as to how many servings per day are recommended. (Exhibit E). However, bHIP's "FUSION WEIGHT MANAGEMENT SYSTEM SAMPLE MENU," states that the user should consume a single serving (referred to as a "FUSION full meal replacement shake") in place of breakfast in the morning. (Exhibit F). The same menu goes on to state that the user should take at mid-morning one capsule with water of a "companion" product sold by bHIP under the brand name "FIX." (Exhibit F). And as a mid-day "snack," the menu suggests the consumer eat celery sticks with peanut butter "OR FUSION shake." (Exhibit F).

One serving, according to the Supplement Facts label, delivers 125 mg of ac-11[®], i.e., only half the Minimum Efficacious Daily Dosage required under the License Agreement. (Exhibits D and E). Accordingly, the FUSION product is unauthorized under the License Agreement just for this reason and is violative thereof.

(iii) the FUSION product line was not licensed

Schedule B of the License Agreement listed certain products that are expressly authorized. (Exhibit D, Schedule B). Schedule B, however, did not permit bHIP to market or offer for sale beverage or meal products containing the ac-11[®] Ingredient. (*Id.*). Indeed, Section

2.4.3 of the License Agreement stated that beverage products containing ac-11[®] are not authorized under the License Agreement. (*Id.* at Section 2.4.3).

Defendant began to offer for sale the meal replacement shake product called the FUSION SHAKE. (Zwiren Dec., ¶12). The product label for the Unauthorized Product states that it is a *Meal Replacement Shake "powered by ac-11*®." (Exhibit E). Because the unauthorized FUSION product does not comply with the terms of the License Agreement, it is not an authorized product.

The FIX Product

bHIP markets the FIX product as a companion product to FUSION. (Exhibit H; Zwiren Dec., ¶36). Optigenex considers FIX to be a product that is inaccurately labeled and did not, and would not, approve the FIX product as presently sold by bHIP in combination with FUSION. (Worth Dec., ¶¶53-59). Although FIX does not contain ac-11[®], it is marketed as a companion product with FUSION in a so-called single product "kit" that was not approved or authorized by Optigenex. (*Id.*).

The FDA provided guidance for the calculation of the daily recommended dietary intake for vitamins, minerals and food components, such as proteins, fats and carbohydrates. (Exhibit I). "Supplement Facts" labels (for dietary supplements) and "Nutrition Facts" labels (for foods) are required to list the nutrients they contain by weight, in accordance with serving size, which the label must specify. (Exhibit I). Moreover, for each nutrient, products must also provide a statement as to the percentage of the daily value. (Exhibit I). The daily value amount above referenced typically is shown on a product label as "% Daily Value." (Exhibit I).

The FIX Supplement Facts label contain the following errors:

- a. Mislabeling of the product's 20 mg content of Vitamin B6 as 50% of the "% Daily Value," when 20 mg of Vitamin B6 is 1,000 percent of the "% Daily Value" established under the aforementioned Guidance for Industry by the FDA (Exhibits H and I; Worth Dec., ¶58);
- b. Mislabeling of the product's 250 mcg (microgram) content of Vitamin B12 as being "100%" of "% Daily Value," when, 250 mcg of Vitamin B12 is in excess of 4,000 percent of "% Daily Value" established by the FDA (Exhibits H and I; Worth Dec.,¶58);
- c. Mislabeling of the product's 32 mg content of Calcium as 125% of "% Daily Value," when32 mg of Calcium is only 3.2 percent of "% Daily Value" established by the FDA(Exhibits H and I; Worth Dec.,¶58);
- d. Mislabeling of the product's 120 mcg content of *Chromium* as being sourced from "zinc glycinate" when, upon information and belief, such sourcing is impossible, because Chromium, an element (symbol *Cr*), originates from Chromite ore (Exhibits J and K); and
- e. Mislabeling of the product's 120 mcg content of Chromium as 60% of "% Daily Value," when, 120 mcg of actual Chromium is 100 percent of "% Daily Value" established by the FDA.(Exhibit I; Worth Dec.,¶58).

bHIP's failure to submit the FIX companion product label for pre-approval renders the FUSION/FIX "kit" unauthorized under the License Agreement. (Worth Dec., ¶53-59). Improper Supplement Facts labeling moreover is a violation of "Good Manufacturing Practices," or GMP, as defined by the FDA for dietary supplement manufacturing. See 72 Fed. Reg. 34752 (June 25, 2007)("Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements").²

Other Products

A number of advertising and marketing materials for the products marketed under the trade names "AEDRE," "PURPLE CAPS," "PURPLE PLUS," "PURPLE STRIPS" and

²In the License Agreement, bHIP represented at Section 3.1.1 that it would "ensure that its manufacturers are listed as cGMP (current Good Manufacturing Practice) compliant in respect of the Authorized Products." (Exhibit D, Section 3.1.1).

"ACTIVAR," all of which are bHIP products containing ac-11[®], have been disseminated to the public by bHIP without prior review or approval by Optigenex. (Exhibits L and M). However, the packaging and labeling of these products is inaccurate. (Worth Dec., ¶¶60-70). Optigenex does not and would not approve of such labeling. (*Id.*). Accordingly, these products are unauthorized under the License Agreement.

IV. Controlling Principals of Law and Argument

A. Standard for Preliminary Injunction

To obtain a preliminary injunction, a party must show (a) irreparable harm and (b) either (1) likelihood of success on the merits or (2) sufficiently serious questions going to the merits to make them a fair ground for litigation and a balance of hardships tipping decidedly toward the party requesting the preliminary relief. *People's United Bank v. PeoplesBank*, 401 Fed. App'x 607 (2d Cir. 2010); *Citigroup Global Mkts., Inc. v. VCG Special Opportunities Master Fund, Ltd.*, 598 F.3d 30, 35 (2d Cir. 2010); *Krispy Kreme Doughnut Corp. v. Satellite Donuts, LLC*, 725 F. Supp. 2d 389, 393 (S.D.N.Y. 2010).

B. Irreparable Harm

In *Power Test Petroleum Distributors, Inc. v. Calcu Gas, Inc.*, the Second Circuit explained the importance of preliminary injunctive relief in the trademark context, stating that irreparable injury "exists in a trademark case when the party seeking the injunction shows that it will lose control over the reputation of its trademark pending trial. 754 F.2d 91, 95 (2d Cir. 1985). Injunctive relief is the appropriate remedy because "[r]eputation is not calculable nor precisely compensable." *Id.* In the context of a trademark infringement case brought by a licensor against a licensee, when unlawful use of the trademark and consumer conFUSION have been demonstrated, a finding of irreparable harm is automatic. *Fido's Fences Inc. v. Canine*

Fence Co., 309 Fed. App'x 480, 482 (2d Cir. 2009); Church of Scientology Int'l v. Elmira Mission of the Church of Scientology, 794 F. 2d 38, 43-44 (2d Cir. 1986). This is because a licensee who once possessed authorization to use the trademarks of its licensor becomes associated in the public's mind with the trademark holder. Fido's Fences Inc., 309 Fed. App'x at 482 (quoting Church of Scientology Int'l, 794 F.2d at 44). In such a case, the need for injunctive relief is compelling because there is an increased danger that customers will be confused and believe that the former licensee is the authorized representative of the trademark holder. Fido's Fences Inc., 309 Fed. App'x at 482.

In the instant case, bHIP is no longer a licensee of Optigenex. Nevertheless, bHIP is marketing and offering for sale products that are unauthorized under the License Agreement. These products are not included in the list of authorized products contained in Schedule B of the License Agreement, contain less than the Minimum Efficacious Daily Dosage required under the License Agreement and have product labeling and packaging that is inaccurate and were never approved by Optigenex. bHIP continues to market and offer for sale these unauthorized products in association with Optigenex's Trademarks, falsely associating these unauthorized products with the quality and quality control consumers expect from ac-11® Products containing the ac-11[®] Ingredient that originate from Optigenex. Optigenex, therefore, has no way to ensure the quality of the unauthorized products being sold in association with the Optigenex Trademarks and without a preliminary injunction, the good will and reputation of Optigenex's Trademarks could, and will, be severely damaged if bHIP is permitted to continue to sell the unauthorized products. Indeed, pursuant to Section 3.7.2 of the License Agreement, Optigenex and bHIP agreed that bHIP's marketing or offering for sale of unauthorized products constitutes irreparable harm to Optigenex, entitling Optigenex to injunctive relief.

C. Likelihood of Success on the Merits

1. Trademark Infringement

Section 43(a) of the Lanham Act prohibits a person from using "any word, term, name, symbol, or device, or any combination thereof ... which ... is likely to cause confusion ... as to the origin, sponsorship, or approval of [the producer's] ... goods, services, or commercial activities by another person." 15 U.S.C. § 1125(a)(1)(A). Hence, a plaintiff in a trademark infringement case seeking a preliminary injunction must establish that the defendant used the plaintiff's valid trademark in a way that is likely to confuse consumers as to the source of the product. *See Lois Sportswear*, *U.S.A.*, *Inc. v. Levi Strauss & Co.*, 799 F.2d 867, 871 (2d Cir. 1986).

Optigenex's Trademarks are registered on the principal register of the United States Patent and Trademark Office and the existence of a trademark registration is *prima facie* evidence of a valid trademark. *Frank Brunckhorst Co. v. G. Heileman Brewing Co., Inc.*, 875 F. Supp. 966, 975 (E.D.N.Y. 1994)(citing *Lois Sportswear, U.S.A., Inc.*, 799 F.2d at 871).

Courts have routinely held that a former licensee's continued use of the licensor's trademarks creates a likelihood of confusion of as a matter of law. *See, e.g., Sunward Elecs., Inc. v. McDonald*, 362 F.3d 17 (2d Cir. 2002)(defendant's continued use of plaintiff's trademarks and trade names and phone listings established likelihood of consumer confusion); *Microban Prods. Co. v. API Indus., Inc.*, No. 14 Civ. 41, 2014 WL 1856471 (S.D.N.Y. May 8, 2014)(when ex-licensee continues to use a mark after its license expires, likelihood of confusion is established as a matter of law); *L & L Wings, Inc. v. Marco-Destin, Inc.*, 676 F. Supp. 2d 179, 188 (S.D.N.Y. 2009)(same). Because the products by definition under the License Agreement are unauthorized, bHIP has no right of inventory sell-off; the limited time continuing right under

the License Agreement to use Optigenex's Trademarks following termination only applies to authorized products.

Here, as discussed above, bHIP has continued to use the ac-11[®] Trademarks without authorization. Moreover, bHIP uses Optigenex's Trademarks in association with products that are not authorized by Optigenex, which the parties agreed constitutes irreparable injury to Optigenex under the License Agreement. Optigenex is, therefore, not only likely to succeed on the merits of this action because the mere use of an authorized trademark is, *per se*, irreparable harm, but also because Optigenex has explained that the mislabeling used by bHIP and why Optigenex would never approve such a product with such mislabeling for distribution. Optigenex is entitled to the injunctive relief requested herein.

2. Breach of License Agreement

As set forth above, bHIP is clearly in breach of the License Agreement by selling products that are not authorized by the License Agreement. Specifically, the unauthorized products are not included in Schedule B of the License Agreement, contain less than the Minimum Efficacious Daily Dosage required under the License Agreement and the product labeling and packaging that were never approved by Optigenex, all of which constitute a breach of the License Agreement. To that end, the License Agreement specifically provides that the marketing and/or offering for sale of unauthorized products constitutes irreparable harm and Optigenex may obtain injunctive relief associated with the sale of such products. Accordingly, there is a likelihood that Optigenex will succeed on the merits of its breach of contract claim against bHIP.

D. Balance of Hardships Tips Decidedly in Favor of Optigenex

Because Optigenex has shown that it is likely to succeed on the merits, it is not necessary

for the Court to consider the balance of the hardships. Nevertheless, the balance of the hardships

weighs decidedly in favor of Optigenex. Optigenex has spent considerable monetary and other

resources in developing its proprietary ac-11® Ingredient and prides itself on the quality of ac-

11[®] Products containing the ac-11[®] Ingredient that are sold in the United States and elsewhere.

Optigenex's consumers rely upon the Optigenex Trademarks as an indicator that ac-11[®] Products

are originating from Optigenex subject to Optigenex's strict quality control standards. bHIP's

marketing and offering for sale of unauthorized products in association with Optigenex's

Trademarks threatens Optigenex's reputation and the trust it has built with its consumers. Under

such circumstances, Optigenex cannot envision any harm to bHIP if the relief requested herein is

granted.

V. Conclusion

For the reasons set forth herein, the Court should grant Optigenex's motion in its entirety

and such other and further relief as this Court deems just and proper.

Dated: Garden City, New York

November 17, 2014

Respectfully submitted,

DAVIDOFF HUTCHER & CITRON LLP

By:

s/Michael A. Adler

Michael A. Adler, Esq. (MA6626) Jonathan E. Temchin, Esq. (JT7609) 200 Garden City Plaza, Suite 315 Garden City, New York 11530

(516)248-6400

Attorneys for Plaintiff

18